**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 99N–4069]**

# Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of Participation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by *[insert date 30 days after date of publication in the* **Federal Register].**

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

## Notice of Participation—21 CFR 12.45 (OMB Control Number 0910–0191)—Extension

Under part 12 (21 CFR part 12) regulations issued under sections 201 to 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 to 393), any interested person may participate in



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a formal evidentiary hearing, either personally or through a representative by filing a notice of participation under § 12.45. Section 12.45 requires that any person filing a notice of participation state the person's specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in § 12.85 or, in the case of a hearing before a public board of inquiry, in 21 CFR 13.25, concerning disclosure of data and information by participants. A participant's appearance can be struck by the presiding officer in accordance with § 12.45(e). The information obtained is used' by the presiding officer and other participants in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation. The affected respondents are individuals or households, State or local governments, not-for-profit institutions and businesses or other for-profit groups and institutions.

In the **Federal Register** of September 28, 1999 (64 FR 52330), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

**TABLE 1 .-ESTIMATED ANNUAL REPORTING BURDEN***

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 12.45 | 30 | 1 | 30 | 3 | 90 |

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

The agency bases this estimate on an average for the period 1996 through 1998 in which each notice of participation filed took an estimated 3 hours to complete.

Dated: December 22. 1999

William K. Hubbard
Senior Associate Commissioner for
Policy, Planning, and Legislation

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